OSMETECH

K011043

510(K) SUMMARY

NOV 3 0 2001

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Contact Name: David Grindrod, Cheif Operating Officer
Date summary was prepared: November 29, 2001

Name of Device

Trade Name:	The Osmetech Microbial Analyser™- Urinary Tract Infection Detector (OMA™-UTI), K011043
Common Name:	Urine screening kit
Classification Name:	Microorganism Differentiation and Identification Device (Product Code JXA) Microbiology Branch
Regulation Number:	866.2660
Device Classification:	This device is a class I device

Identification of Predicate Devices

1. Uriscreen™, Diatech Diagnostics, Inc.; K981084, Product Code JXA
2. Standard Culture in urine

Device Description

The OMA™-UTI uses "electronic nose" technology for the detection of volatile compounds released from microorganisms in human specimens. The principle is based on the release of volatile compounds from bacteria into the headspace (the volume above the liquid samples) of clinical samples. The volatile compounds are detected by an array of gas sensors based on patented conducting polymer technology.

STATEMENT OF INTENDED USE

The Osmetech Microbial Analyser™ - Urinary Tract Infection Detector (OMA™-UTI) is an automated *in-vitro* diagnostic device intended for use to indirectly measure bacterial presence by semi-quantitative analysis of volatile compounds released into the headspace above a urine sample. The OMA™-UTI is indicated for use by clinical laboratory healthcare professionals for screening of urine specimens for determination of bacteriuria of $\geq 10^5$ CFU/mL.

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The OMA™-UTI is not capable of providing results for evidence of bacteriuria below the 10^5 CFU/mL threshold. Laboratories requiring information on patients for which results below 10^5 CFU/mL are significant should use an alternate method.

SUBSTANTIAL EQUIVALENCE COMPARISON

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness of the OMA™-UTI, the OMA™-UTI has been compared to the Uriscreen™ device (Diatech Diagnostics, Inc.; K981084) and Standard Culture in urine.

Intended Use of the OMA™-UTI and Predicate Devices

A review of the intended use of the OMA™-UTI and the Uriscreen™ systems shows them to be essentially the same in that they are capable of determining if a urine sample is positive or negative for UTI based on the production of compounds by bacteria in urine.[1] Both devices yield a positive or negative result for bacteriuria (defined as $\geq 1\times10^5$ CFU/ml in urine), based on an indirect measure of bacteria in urine.

The difference in the intended use statements of the OMA™-UTI and the Uriscreen™ is that the OMA™-UTI is designed for professional use only, while the Uriscreen™ may be used by consumers. This difference does not impact on safety or effectiveness of the OMA™-UTI device.

Technological Characteristics of the OMA™-UTI and Predicate Devices

The OMA™-UTI and the Uriscreen™ devices monitor compounds released from bacteria in urine. However, the compounds measured are different, and the technology for measurement is different. The Uriscreen™ is a manual test - a tablet is added to the urine specimen to determine bacterial presence by detecting catalase in bacteria and white blood cells, whereas the OMA™-UTI is an automated procedure detecting volatile metabolites released from bacteria into the urine. Hence, a clinical trial was conducted to establish that the technological differences had no adverse effect on safety and effectiveness of the OMA™-UTI.

Clinical Performance Data

Urine test results with the OMA™-UTI were compared to results using the Standard Culture technique (the "gold standard" for measurement of bacteria in urine) in 1038 urine samples from three Clinical Laboratories (two U.S. and one non-U.S. sites) for assessment of UTI. Based on our protocol criteria a positive culture was considered $\geq 1\times10^5$ CFU/ml for either single colonies

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[1] The statement of intended use for the Uriscreen™ device is as follows: "Uriscreen is a non quantitative rapid screen for the detection of Urinary Tract Infection. Uriscreen detects both bacteria and/or white blood cells, common indicators of Urinary Tract Infection."

or for mixed colonies containing at least one predominant organism $\geq 1 \times 10^5$ CFU/ml. From this clinical trial the following performance characteristics were calculated:

Sensitivity	81.0% (95% CI 73.7% to 87.0%)
Specificity	83.1% (95% CI 80.4% to 85.5%)
PPV	44.1% (95% CI 38.1% to 50.2%)
NPV	96.4% (95% CI 94.8% to 97.6%)
Accuracy	82.8% (95% CI 80.3% to 85.0%)

These data indicate that the performance values of the OMA™-UTI compare favorably with the predicate device, Uriscreen™ (K981084), which reported a sensitivity of 95%, specificity of 73%, and accuracy of 80%.

Other Clinical Data
An inter-site reproducibility study (two U.S. sites) was conducted using 249 samples to determine reproducibility of OMA™-UTI at two clinical sites. Results of this study showed very good agreement between sites (kappa 0.86, 95%CI 0.80-0.92).

Interference Studies
In addition, tests of interfering substances were conducted, revealing that there was no effect of blood or specific gravity in clinical samples on the performance of the OMA™-UTI. Laboratory bench testing indicates that sodium nitrite may interfere with OMA™-UTI test results by causing a negative sample to have a positive result.

CONCLUSIONS

When comparing the OMA™-UTI to the predicates, it can be concluded with the results of the pivotal clinical trial and other studies that the OMA™-UTI is substantially equivalent to the Uriscreen™ and to Standard Culture techniques in urine. Based on the establishment of substantial equivalence, the safety and effectiveness of the OMA™-UTI is confirmed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. James White
Chief Executive Officer
Osmetech plc
Electra House, Electra Way
Crewe, CW1 6WZ
United Kingdom

NOV 3 0 2001

Re: K011043
Trade Name: Osmetech Microbial Analyser™- Urinary Tract Infection Detector
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: Class I
Product Code: JXA
Dated: November 15, 2001
Received: November 19, 2001

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE / INTENDED USE STATEMENT

510(k) Number (if known): K011043

Device Name: The Osmetech Microbial Analyser™- Urinary Tract Infection Detector

Indications for Use/Intended Use:

The Osmetech Microbial Analyser™ - Urinary Tract Infection Detector (OMA™-UTI) is an automated *in-vitro* diagnostic device intended for use to indirectly measure bacterial presence by semi-quantitative analysis of volatile compounds released into the headspace above a urine sample. The OMA™-UTI is indicated for use by clinical laboratory healthcare professionals for screening of urine specimens for determination of bacteriuria of $\geq 10^5$ CFU/mL.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PERSCRIPTION USE ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Freddie L. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011043